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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2005N-0413

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the October 19, 2005 Federal Register Notice Assessing Consumer Perceptions of Health Claims; Public Meeting Request for Comments. 70 Fed. Reg. 60749.

NNFA is a trade association representing the interests of more than 8,000 retailers, manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products throughout the United States. NNFA appreciates the opportunity to comment on the questions posed by FDA regarding the consumer perception of health claims on dietary supplements.

NNFA strongly believes in the utility of health claims for both manufacturers and consumers. Health claims can be an effective marketing tool for those seeking to distribute "good for you" food products, while at the same time offering important information and food choices for consumers seeking these foods.

Data from the Natural Marketing Institute's (NMI) 2004 Health & Wellness Trends Database™ indicate that a majority of consumers (61%) agree that it is important to have foods that bear a specific health claim. A strong majority (68%) also agree that printed health claims make purchasing decisions easier[1]. As the number of foods available for health claims steadily increases, FDA should be providing consumers with the comprehensible information they desire to make decisions about foods they need and want.

Unfortunately, the verbiage adopted by FDA for both the full and qualified health claims has resulted in an underutilization of this type of information, despite strong consumer demand. Manufacturers find the health claims language cumbersome and conflicting. In addition, the qualified health claim language adopted by FDA in most cases, and studied for the Working Paper, does not reflect the specific state of the science, but rather is standardized to fit a few defined scenarios based upon the level of science submitted. As a result, consumers are either being confused by the wordy claims or are

[1] NMI's Health and Wellness Trends Database™ is an annual research study of 2,000+ U.S. consumers. www.NMIsolutions.com

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not being provided with health claim information even in instances when it may be available, as manufacturers choose to forego, rather than utilize, such label claims.

In addition, NNFA believes that FDA's assessment of consumer perception, made available in the context of this Request for Comments, confirms that the disqualifying language utilized by FDA most frequently to date is unhelpful to consumers. FDA has not, however, tested other possible disclaimer language (adopted by FDA in some of the more recent qualified health claims scenarios) which may be more meaningful, relevant to the state of the science, and thus useable to consumers seeking this information.

Finally, NNFA believes that manufacturers are also hesitant to request a health claim because of FDA's lack of responsiveness within appropriate time frames. NNFA believes FDA must spend the resources necessary to timely review and allow health claims, or the entire process frustrates ingredient development and market entry decisions and thus is without value to those seeking to entertain their use.

Pearson History Background

In 1994, following the issuance of the Nutrition Labeling and Education Act of 1992 (NLEA) and the Dietary Supplement Health and Education Act of 1994 (DSHEA), FDA issued a rule setting requirements for health claims on dietary supplements. 59 Fed. Reg. 395 (1994). This rule authorized a health claim on a supplement only if there was significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims that such claim was supported by the totality of publicly available scientific evidence.

Under this rule, FDA initially refused to authorize a number of petitioned health claims, including those for: (1) dietary fiber and cancer; (2) antioxidant vitamins and cancer; (3) omega-3 fatty acids and coronary heart disease; and (4) a comparative claim that 0.8 mg folate in dietary supplement form is more effective in reducing the risk of neural tube defects than a lower amount in conventional food form.

FDA's rationale for denying these claims was challenged in Pearson v. Shalala, a case filed in the District of Columbia. Although the district court ruled in FDA's favor, 14 F. Supp. 2d 10 (D.D.C. 1998), the Court of Appeals for the D.C. Circuit reversed the lower court's decision, 164 F. 3d 650 (D.C. Cir. 1999). The appeals court held that the 1st Amendment does not permit FDA to reject health claims on grounds that they are potentially misleading unless the agency also determines that no disclaimer would eliminate the problem. At that time, the court also directed FDA to define "significant scientific agreement."[2]

The Court in Pearson described the types of disclaimers that it felt would be meaningful for consumers. The Court recommended very "ingredient specific" language tailored to the scientific presentation made by the petitioner. It did not recommend a standard recipe of disclaimer language that would be triggered when a certain level of

[2] FDA, despite its December 22, 1999 Guidance for Industry, Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, has yet to adopt such a definition.

science was presented, which is what FDA has, since Pearson, imposed on most petitioners seeking health claims. The following is a quote from the Pearson case which directs FDA to consider "ingredient specific" disclaimers:

> Our rejection of the government's position that there is no general First Amendment preference for disclosure over suppression, of course, does not determine that any supposed weaknesses in the claims at issue can be remedied by disclaimers and thus does not answer whether the subregulations, 21 C.F.R. § 101.71(a), (c), (e); id. § 10179(c)(2)(i)(G), are valid. The FDA deemed the first three claims—(1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers," (2) "Consumption of fiber may reduce the risk of colorectal cancer," and (3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease"—to lack significant scientific agreement because existing research had examined only the relationship between consumption of foods containing these components and the risk of these diseases. The FDA logically determined that the specific effect of the component of the food constituting the dietary supplement could not be determined with certainty. (The FDA has approved similar health claims on foods containing these components. See, e.g., 21 C.F.R. § 101.79 (folate-neural tube defects).) **But certainly this concern could be accommodated, in the first claim for example, by adding a prominent disclaimer to the label along the following lines: "The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods." A similar disclaimer would be equally effective for the latter two claims.** 164 F.3d at 658. (emphasis added)

FDA argued to the court that the type of disclaimer recommended would cause consumer confusion -- yet they offered no consumer data or evidence that it did.

> **The government disputes that consumers would be able to comprehend appellants' proposed health claims in conjunction with the disclaimers we have suggested--this mix of information would, in the government's view, create confusion among consumers. But all the government offers in support is the FDA's pronouncement that "consumers would be considerably confused by a multitude of claims with differing degrees of reliability."** 59 Fed. Reg at 405. Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech—here the FDA's conclusory assertion falls far short. See Ibanez, 512 U.S. at 146 ("If

the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.") (citations and internal quotation marks omitted); Edenfield, 507 U.S. at 771 (invalidating a ban on in-person solicitation by accountants where the government failed to present "studies" or "anecdotal evidence" showing that such solicitation posed dangers of fraud, overreaching, or compromised independence).

**We do not presume to draft precise disclaimers for each of appellants' four claims; we leave that task to the agency in the first instance.** 164 F.3d at 659. (emphasis added)

Now, FDA makes a request to industry to provide the type of evidence it lacked in the Pearson case and continues to lack today. FDA supports this request with a Working Paper on the Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claim, by FDA's Division of Social Sciences. In brief, that paper investigates a number of different approaches to conveying information about the certainty of scientific evidence supporting a health claim. The study used two verbal schemes and two "report card grade" systems to express the disclaimer language. *However, all four used the same four-level system to classify health claims in terms of the strength of the science, and included the same standardized disclaimer language utilized most often by FDA for qualified health claims (no disclaimer, "promising but not conclusive", "limited and inconclusive" or "very limited and preliminary").* The study found that the text sentences using adjectives do not correctly convey the intended strength of the science, and that the report cards, while addressing the strength of the science, caused greater confusion as to the perception of scientific certainty relative to unqualified claims.

The study did not explore the type of ingredient/science-specific disclaimers directed by the Pearson case. NNFA believes very strongly that consumers do not understand the disclaimer language studied by FDA because it is too qualified and not specific enough. FDA should have explored a claim with the type of disclaimer suggested by the court.[3] (**The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods**

[3] FDA now seems to be recognizing the utility of such "expanded" qualified health claims. In its most recent enforcement discretion letters on qualified health claims, it now appears to be adopting the approach recommended by Pearson: e.g., One study suggests that consumption of tomato sauce two times per week may reduce the risk of ovarian cancer; while this same study shows that consumption of tomatoes or tomato juice had no effect on ovarian cancer risk. FDA concludes that it is highly uncertain that tomato sauce reduces the risk of ovarian cancer; four studies did not show that tomato intake reduces the risk of gastric cancer, but three studies suggest that tomato intake may reduce this risk. Based on these studies, FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer; one study suggests that consuming tomatoes does not reduce the risk of pancreatic cancer, but one weaker, more limited study suggests that consuming tomatoes may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that tomatoes reduce the risk of pancreatic cancer.

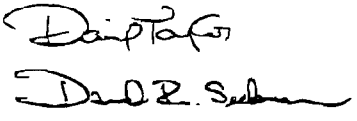
**on reducing the risk of cancer may result from other components in those foods.)** In NNFA's view, is likely that consumers would have understood and appreciated that type of claim.

We believe that consumers will welcome educational disclaimer language that is relevant to the ingredient and the science on the ingredient, rather than standardized language that is vague and unclear. In terms of the educational element, the Mintel study also acknowledged the value of education in terms of helping consumers understand and seek out health claims information of food labels, particularly in the black and Hispanic communities. NNFA echoes these goals – education is a known component to any new regulatory scheme. Without it, consumers are "left in the dark" as to why, for example, one claim bears a disclaimer and another does not or why the disclaimer language is different. Whatever FDA decides to do in terms of the procedures by which it will review health claims and approve/exercise enforcement discretion, and however they ultimately phrase these claims, consumer comprehension is tightly linked to an educational component. FDA resources must be dedicated to that aspect of any new approach, as it has yet to happen with respect to qualified health claims.

NNFA appreciates this opportunity to submit these comments.

Respectfully submitted,

NATIONAL NUTRITIONAL FOODS ASSOCIATION



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